



Cooled Radiofrequency Treatment

for Chronic Back, Knee and Hip Pain

Frequently Asked Questions

July 2017

Imagine where life could take your patients

COOLIEF* Cooled Radiofrequency (RF) Treatment for Chronic Back, Knee and Hip Pain

About COOLIEF* Cooled Radiofrequency

How COOLIEF* Cooled RF Works

Only known **minimally-invasive, thermal radiofrequency pain management system using *water-cooled technology*** to safely deactivate *difficult-to-reach* pain-causing sensory nerves in the spine, knee and hip.

A radiofrequency generator transmits a small current of RF energy through an insulated electrode – or probe - placed within tissue. Ionic heating, produced by the friction of charged molecules, **thermally** deactivates the nerves responsible for sending pain signals to the brain.

First and only thermal RF treatment to be FDA-Cleared specifically to relieve osteoarthritis (OA) knee pain.

By delivering RF energy through ***water-cooled electrodes***, thermal RF energy is safely transmitted to create **large volume, spherically-shaped treatment areas**, providing physicians the **flexibility to use the best approach angle** to reach target nerves located within complex nerve courses.

Clinically proven to provide up to **24 months of pain relief**; improved physical functionality, and reduced drug utilization.

Procedure time varies depending on the physician and the treatment needed, but according to physicians who have performed the COOLIEF Cooled RF procedure, the actual **treatment time is less than one hour**.

Provides significantly **greater and longer-lasting pain relief, improved physical function and higher patient satisfaction than intra-articular steroid injections** ⁵

Unlike surgery, COOLIEF Cooled RF involves no incision. Since this minimally invasive, outpatient treatment requires no general anesthesia, **patients should be able to return home shortly after the treatment**.

Manufactured by Halyard Health, Halyard is committed to addressing some of today's most important healthcare needs, such as reducing the use of opioids while helping patients move from surgery to recovery.

Must be administered by a COOLIEF-trained physician.

⁵ Halyard Health Inc. sponsored study: A Prospective, Multi-Center, Randomized, Clinical Trial Evaluating the Safety and Effectiveness of Using COOLIEF™ Cooled Radiofrequency Probe to Create Lesions of the Genicular Nerves and Comparing Corticosteroid Injection in the Management of Knee Pain. Final results 03Apr2017. Study available upon request from Halyard.

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Treating Osteoarthritis Knee Pain

Treating Chronic Back and Hip Pain

In April 2017, COOLIEF* Cooled RF became the first and only thermal RF treatment to be **FDA cleared to relieve chronic moderate to severe knee pain caused by osteoarthritis (OA)**.

FDA-Clearance was based on results from a 151-patient prospective, randomized multi-center study comparing COOLIEF* Cooled RF to intra-articular steroid injections in patients suffering from knee pain due to osteoarthritis. The study found that at six months, COOLIEF* Cooled RF provided **significantly greater and longer-lasting pain relief, improved physical function and higher patient satisfaction than intra-articular steroid injections**.⁵

According to the Centers for Disease Control and Prevention, **OA affects over 30 million adults in the U.S.**, and its prevalence is on the rise as both the age and weight of Americans continue to increase.^{1,2}

Surgery can be beneficial in properly selected patients. However, due to BMI, age, other co-morbidities or invasiveness, **surgery isn't for everyone**.

Surgery can help some patients with chronic knee pain who **wait an average of nine years until they are ready or qualify for knee replacement surgery**.³

Treatments for chronic OA knee pain include nonsteroidal anti-inflammatory drugs, opioids and steroid injections, but these provide only short-term relief.⁴

Four out of five adults in the United States experience chronic lower back pain³ and Americans spend at least \$50 billion each year trying to treat it.⁴

Traditional treatments for chronic back pain include oral anti-inflammatory medications, steroid injections, physical therapy, standard radiofrequency ablation and joint fusion or other surgery.

Medications do not effectively target nerves that cause pain and can lead to side effects such as nausea, grogginess, and addiction.

Surgery can be beneficial in properly selected patients. However, due to BMI, age, other co-morbidities or invasiveness, surgery isn't for everyone.

¹ Osteoarthritis Fact Sheet [Internet]. CDC.gov. Centers for Disease Control and Prevention; 2017 [cited 2017Apr12]. Available from: <https://www.cdc.gov/arthritis/basics/osteoarthritis.htm>

² Bliddal H, Christensen R. The treatment and prevention of knee osteoarthritis: a tool for clinical decision-making. Expert Opinion on Pharmacotherapy. 18 June 2009; 10(11):1793-804.

³ KS&R. Halyard sponsored study: Osteoarthritis Pain Landscape & Patient Journey. 2015. Data on file.

⁴ AAOS - American Academy of Orthopedic Surgeons. Opioid Use, Misuse, and Abuse in Orthopaedic Practice. Information Statement 1045.

⁵ Halyard Health Inc. sponsored study: A Prospective, Multi-Center, Randomized, Clinical Trial Evaluating the Safety and Effectiveness of Using COOLIEF™ Cooled Radiofrequency Probe to Create Lesions of the Genicular Nerves and Comparing Corticosteroid Injection in the Management of Knee Pain. Final results 03Apr2017. Study available upon request from Halyard.

⁶ Davis T. Cooled RF Ablation Superior to Corticosteroids in Knee Osteoarthritis. Pain Medicine News [Internet]. 2017Feb2; Available from: <http://www.painmedicineneeds.com/Multimedia/Article/02-17/Cooled-RF-Ablation-Superior-to-Corticosteroids-in-Knee-Osteoarthritis/40262/ses=ogst?enl=true>